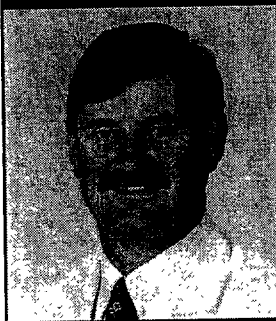


**Community Consultation
Documents**

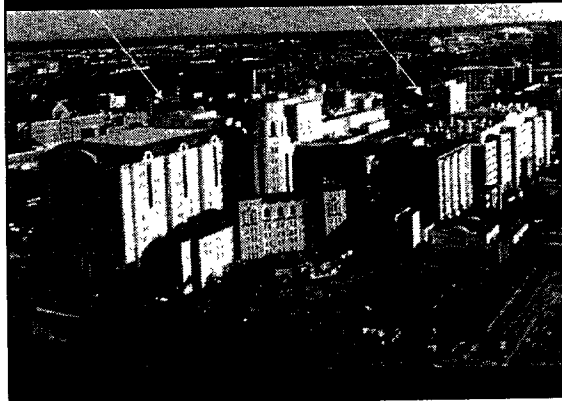
Frederick A. Moore, M.D.



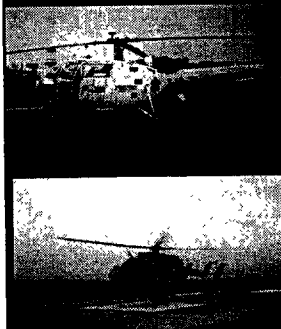
Medical Director
Trauma Service
Memorial Hermann Hospital

Chief, General Surgery
University of Texas
Houston Medical School

MEMORIAL HERMANN HOSPITAL UT HOUSTON MEDICAL SCHOOL



LIFE FLIGHT
FOUNDED IN 1976

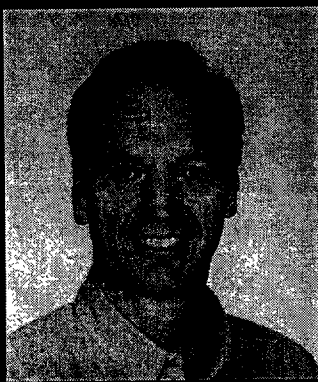


Dr James H "Red" Duke Jr





Rosemary A. Kozar, M.D., Ph.D.
Trauma Surgeon
Memorial Hermann Hospital
Associate Professor of Surgery
University of Texas
Houston Medical School



Bruce A. McKinley, Ph.D.
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Surgery
University of Texas
Houston Medical School



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Trauma Surgeon
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University of Texas
Houston Medical School

NORTHFIELD LABORATORIES STUDY SPONSOR

Developer of the blood substitute *PolyHeme*[®]
Conducted multiple studies with *PolyHeme*[®]
Most studies have been in severely injured patients

PURPOSE OF STUDY

To compare *PolyHeme*[®] to standard of care

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To compare *PolyHeme*® to standard of care treatment of “hemorrhagic shock” in severely

PURPOSE OF STUDY

To compare *PolyHeme*® to standard of care treatment of “hemorrhagic shock” in severely injured patients starting at the scene of injury

WHAT IS HEMORRHAGIC SHOCK?

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Hemorrhagic: massive bleeding

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Hemorrhagic: massive bleeding

Shock: life-threatening condition

Dangerously low blood pressure

Internal organs don't receive enough oxygen

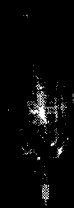
May cause death of severely injured patients

WHAT IS THE STANDARD OF CARE?

WHAT IS THE STANDARD OF CARE? AT SCENE & IN THE HELICOPTER?

Lactated Ringer's

"Salt Water"



WHAT IS THE STANDARD OF CARE? AT SCENE & IN THE HELICOPTER?

Lactated Ringer's

"Salt Water"

Problem: salt water does not carry oxygen



WHAT IS THE STANDARD OF CARE? AT SCENE & IN THE HELICOPTER?

Lactated Ringer's

"Salt Water"

Problem: salt water does not carry oxygen



Without oxygen internal organs do not work
and severely injured patients may die

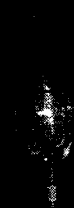
WHAT IS THE STANDARD OF CARE? IN THE HOSPITAL?

WHAT IS THE STANDARD OF CARE? IN THE HOSPITAL?

Lactated Ringer's

Plus

Banked Blood



WHAT IS THE STANDARD OF CARE? IN THE HOSPITAL?

Problems

Banked Blood



WHAT IS THE STANDARD OF CARE? IN THE HOSPITAL?

Problems

Needs to be "cross matched"
to the patient (45 minutes)

Banked Blood



WHAT IS THE STANDARD OF CARE? IN THE HOSPITAL?

Problems

Needs to be "cross matched"
to the patient (45 minutes)

Needs to be refrigerated &
has limited lifespan (42 days)

Banked Blood



WHAT IS THE STANDARD OF CARE? IN THE HOSPITAL?

Problems

Needs to be "cross matched"
to the patient (45 minutes)

Needs to be refrigerated &
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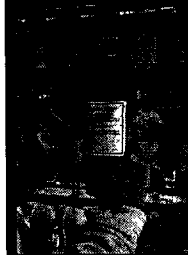
Risks of transmitting viral
diseases (hepatitis and HIV)

Banked Blood



WHAT IS POLYHEME[®]?

Blood substitute that carries oxygen



WHAT IS POLYHEME[®]?

Blood substitute that carries oxygen

1 unit *PolyHeme*[®] = 1 unit of blood

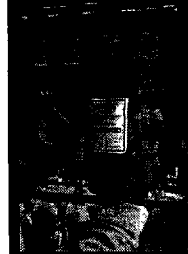


WHAT IS POLYHEME[®]?

Blood substitute that carries oxygen

1 unit *PolyHeme*[®] = 1 unit of blood

Made from human blood



WHAT IS POLYHEME®?



Blood substitute that carries oxygen

1 unit *PolyHeme*® = 1 unit of blood

Made from human blood

Compatible with all blood types

WHAT IS POLYHEME®?



Blood substitute that carries oxygen

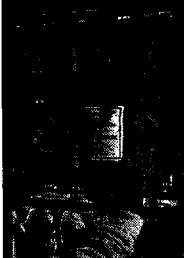
1 unit *PolyHeme*® = 1 unit of blood

Made from human blood

Compatible with all blood types

Immediately available & long shelf life

WHAT IS POLYHEME®?



Blood substitute that carries oxygen

1 unit *PolyHeme*® = 1 unit of blood

Made from human blood

Compatible with all blood types

Immediately available & long shelf life

Reduced risk of viral diseases

EXPERIENCE WITH POLYHEME®

5 clinical trials with > 300 treated patients

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5 clinical trials with > 300 treated patients

Extensively studied in hospitalized trauma patients

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Carries as much oxygen as banked blood

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5 clinical trials with > 300 treated patients

Extensively studied in hospitalized trauma patients

Carries as much oxygen as banked blood

Reduces the need for banked blood transfusion

Shown to be quite safe

Has kept patients alive who have lost all of their own blood

TRIAL DESIGN AT THE SCENE OF INJURY

Severely injured trauma patients
will be assigned to one of two treatments by chance

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Standard of Care

Standard of Care

PolyHeme[®]

TRIAL DESIGN AT THE SCENE OF INJURY

Severely injured trauma patients
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Standard of Care

Standard of Care

PolyHeme[®]

Primary Endpoint
Mortality at 30 days

TRIAL DESIGN AT THE SCENE OF INJURY

Severely injured trauma patients
will be assigned to one of two treatments by chance



Secondary Endpoints
Units of banked blood transfused
Incidence multiple organ failure
Adverse events related to treatment

INFUSION IN HELICOPTER

Salt Water



PolyHeme

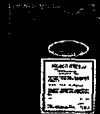


INFUSION IN HOSPITAL

Banked Blood

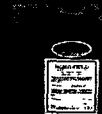


PolyHeme



MAXIMUM INFUSION

PolyHeme



6 units of PolyHeme in 1st 12 hrs

INFORMED CONSENT

Traditionally required for all research studies that
compare two treatments (standard vs. investigational)

Patients are informed of the potential risks and potential
benefits associated with each of these treatments

Patients choose whether to participate in the study

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WAIVER OF CONSENT

Patients are enrolled in a research study without
giving their informed consent

A federal regulation (21 CFR 50.24)
created in 1996

Research study must meet the specific criteria

Patients' lives must be at risk

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Patients are unable to give consent

Potential risks are reasonable

Participation in the research may provide a direct
benefit to the patient

The research could not be practicably carried out
without an exemption

The Food and Drug Administration (FDA) is the federal agency that regulates investigational studies

The FDA has agreed to permit the performance of this study by "Waiver of Consent"

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The Institutional Review Board (IRB) is a group of medical, scientific, and nonscientific members of the local community

The FDA has agreed to permit the performance of this study by "Waiver of Consent"

The IRB reviews and approves all research on humans and has a primary responsibility to assure patient welfare and safety

The FDA has agreed to permit the performance of this study by "Waiver of Consent"

The IRB at UT Houston has approved this research study pending adequate and favorable community consultation

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This presentation is part of our community consultation

CONSENT SAFEGUARDS

If possible, the patient or a legally authorized representative (LAR) will be asked to give consent before the patient is enrolled in the study



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The patient, family members, or a legally authorized representative may decide to withdraw the patient at any time

Questions?